


INFORMATION DISCLOSURE STATEMENT  Address to: Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	CHOR-001
	First Named Inventor	GRANOFF, DAN M.
	Application Number	09/917,222
	Filing Date	July 27, 2001
	Group Art Unit	1645
	Examiner Name	ZEMAN, ROBERT A.
	Title:	<i>"VACCINES FOR BROAD SPECTRUM PROTECTION AGAINST DISEASES CAUSED BY NEISSERIA MENINGITIDIS"</i>

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. This is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or *after* the mailing date of the first Office Action on the merits, whichever event occurred last, but *before* the mailing date of either a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.

A Form PTO-SB/08A listing the references accompanies this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

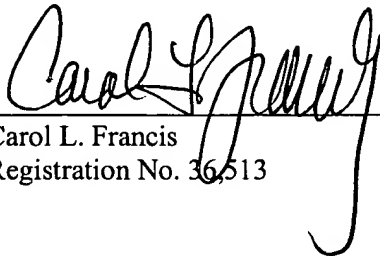
- X All of the references identified herein are being submitted prior to the final determination on patentability by the Office.
- All of the references identified herein were cited in an International (PCT) Search Report dated *, in a PCT application corresponding to the above-identified U.S. application. A copy of the Search Report, including an indication of the purported relevance of the cited documents, is enclosed herewith. Copies of the references are submitted herewith.
- All of the references identified herein were disclosed in parent application Serial No. 60/221,495 and, as such, copies thereof are not included pursuant to the provisions of 37 C.F.R. §1.98(d), except if noted below.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

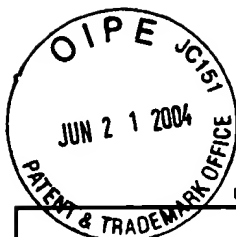
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Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: June 21, 2004

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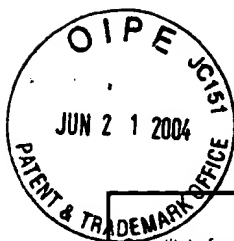
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	C1	Artenstein MS, et al, "Prevention of meningococcal disease by group C polysaccharide vaccine." N Engl J Med 1970;282:417-20.	
	C2	Balmer P, et al, "Serologic correlates of protection for evaluating the response to meningococcal vaccines," Expert Rev Vaccines 2004;3:77-87	
	C3	Borrow R, et al, "Serological basis for use of meningococcal serogroup C conjugate vaccines in the United Kingdom: reevaluation of correlates of protection," Infect Immun 2001;69:1568-73.	
	C4	Densen P., "Interaction of complement with Neisseria meningitidis and Neisseria gonorrhoeae," Clin Microbiol Rev 1989;2 Suppl:S11-7	
	C5	De Wals P, et al, "Effectiveness of a mass immunization campaign against serogroup C meningococcal disease in Quebec," Jama 2001;285:177-81.	

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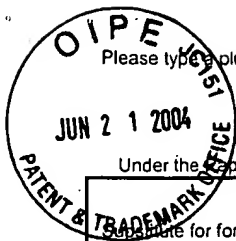
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C6	Figueroa JE, et al, "Infectious diseases associated with complement deficiencies," Clin Microbiol Rev 1991;4:359-95.
C7	Fijen CA, et al, "Complement deficiencies in patients over ten years old with meningococcal disease due to uncommon serogroups," Lancet 1989;2:585-8.
C8	Frasch CE. "Meningococcal Vaccines: Past, Present and Future," In: Cartwright K, ed. Meningococcal Disease. New York: John Wiley & Sons, 1995:245-83
C9	Gold R, et al, "Meningococcal infections. 2. Field trial of group C meningococcal polysaccharide vaccine in 1969-70," Bull World Health Organ 1971;45:279-82
C10	Goldschneider I, et al, "Human immunity to the meningococcus. II. Development of natural immunity," J Exp Med 1969;129:1327-48.
C11	Harris SL, et al, "Age-related disparity in functional activities of human group C serum anticapsular antibodies elicited by meningococcal polysaccharide vaccine," Infect Immun 2003;71:275-86
C12	Holst et al., Serum bactericidal activity correlates with the vaccine efficacy of outer membrane vesicle vaccines against <i>Neisseria meningitidis</i> serogroup B disease. Vaccine 2003, 21:734-737
C13	Maslanka SE, et al. "Age-dependent <i>Neisseria meningitidis</i> serogroup C class-specific antibody concentrations and bactericidal titers in sera from young children from Montana immunized with a licensed polysaccharide vaccine," Infect Immun 1998;66:2453-9.
C14	Milagres LG, et al., "Immune response of Brazilian children to a <i>Neisseria meningitidis</i> serogroup B outer membrane protein vaccine: comparison with efficacy," Infect Immun 1994;62:4419-24.
C15	Moe et al., Differences in surface expression of NspA among <i>Neisseria meningitidis</i> group B strains. Infect Immun 1999 67:5664-75
C16	Nicholson A, Lepow IH. "Host defense against <i>Neisseria meningitidis</i> requires a complement- dependent bactericidal activity," Science 1979;205:298-9.
C17	Pollard AJ, et al, "Development of natural immunity to <i>Neisseria meningitidis</i> ," Vaccine 2001;19:1327-46.
C18	World Health Organization. Requirements for meningococcal polysaccharide vaccine (requirements for biological substances no. 23). WHO Tech Rep Ser 1976;594:72 - 73
C19	50 Fed. Reg. 162, Guidelines for Production of Meningococcal Polysaccharide Vaccines Docket No. 84D-0263, Notice of Availability Published August 21, 1985

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	AA	4,601,903		Frasch	07-22-1986	
	AB	4,727,136		Jennings, et al.	02-23-1988	
	AC	5,705,161		Van Der Ley et al.	01-06-1998	

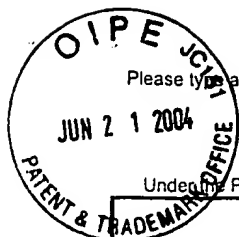
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	AI		WO 98/02547		Nassif et al.	01/22/98		
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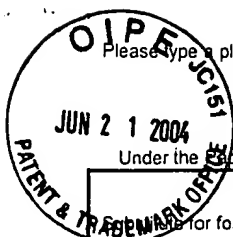
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	AO	ASHTON, F. E. et al., 1938, "A New Serogroup (L) of <i>Neisseria meningitidis</i> ", <i>J. Clin. Microbiol.</i> 17: 722-727.	
	AP	BORROW, et al., 2001, "Serological Basis for Use of Meningococcal Serogroup C Conjugate Vaccines in the U.K.: Reevaluation of Correlates of Protection", <i>Infection and Immunity</i> , 69(3):1568-1573.	
	AQ	BRANHAM, S. E., 1956, "Milestones in the History of Meningococcus", <i>Canadian Journal of Microbiology</i> , 2:175-188.	
	AR	CAMPAGNE et al. 2000, "Safety and immunogenicity of three doses of a <i>Neisseria meningitidis</i> A + C diphtheria conjugate vaccine in infants from Niger", <i>Pediatric Infectious Disease Journal</i> , 19(2):144-150.	
	AS	CARTWRIGHT K et al, 1999, "Immunogenicity and reactogenicity in UK infants of a novel meningococcal vesicle vaccine containing multiple class 1 (PorA) outer membrane proteins", <i>Vaccine</i> , 17:2612-2619.	
	AT	DE KLEINJN ED et al, 2000, "Immunogenicity and safety of a hexavalent meningococcal outer membrane-vesicle vaccine in children of 2-3 and 7-8 years of age", <i>Vaccine</i> , 18:1456-1466.	
	AU	FRASCH, C. E. AND CHAPMAN, 1973, "Classification of <i>Neisseria meningitidis</i> Group B into Distinct Serotypes. III. Application of a New Bactericidal-Inhibition Technique to Distribution of Serotypes among Cases and Carriers" <i>Journal of Infectious Disease</i> , 127:149-154.	
	AV	FUSCO et al., 1997, "Preclinical Evaluation of a Novel Group B Meningococcal Conjugate Vaccine that Elicits Bactericidal Activity in both Mice and Nonhuman Primates", <i>Journal of Infectious Diseases</i> , 175: 364-372.	
	AW	GOLD et al., 1969-1970, "Meningococcal Infections" <i>Bull. WHO</i> , 45: 272-282.	
	AX	GOLDSCHNEIDER et al, 1969, "Human Immunity to the Meningococcus: I. The Role of the Humoral Antibodies" <i>J. Exp. Med.</i> 129:1307-1326.	
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	AZ	GRANOFF et al., 1998, "Bacterial Monoclonal Antibodies That Define Unique Meningococcal B Polysaccharide Epitopes That Do Not Cross-React with Human Polysialic Acid", <i>J. Immunol.</i> 160: 5028-5036.	
	BA	GRANOFF et al., 1998, "Induction of Immunologic Refractoriness in Adults by Meningococcal C Polysaccharide Vaccination", <i>J. Infect. Dis.</i> 178(3): 870-4.	

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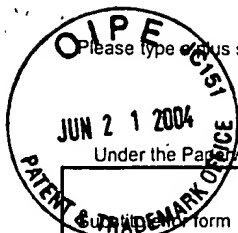
BB	HANKINS, 1982, "Clinical and Serological Evaluation of a Meningococcal Polysaccharide Vaccine Groups A,C,Y, and W135 (41306), <i>Proc. Soc. Biol. Med.</i> 169: 54-57.
BC	JENNINGS et al., 1981, "Inhibitory Effect of K-76 Monocarboxylic Acid, an Anticomplementary Agent, on the C3b Inactivator System" <i>J Immunol.</i> 127:104-108
BD	MACDONALD et al., 1998, "Induction of Immunologic Memory by Conjugated vs. Plain Meningococcal C Polysaccharide Vaccine in Toddlers", <i>JAMA</i> 280:1685-1689
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BF	MACLENNAN et al., 2000, "Safety, Immunogenicity, and Induction of Immunologic memory by a Serogroup C Meningococcal Conjugate Vaccine in Infants" <i>JAMA</i> 283: 2795-2801
BG	MAIDEN et al., 1998, "Multilocus sequence typing: A portable approach to the identification of clones within populations of pathogenic microorganisms", <i>Proc. Natl. Acad. Sci. USA</i> 95:3140-3145.
BH	MARTIN et al., 2000. "Candidate <i>Neisseria meningitidis</i> NspA vaccine", <i>J. Biotechnol.</i> 83:27-31
BI	MARTIN et al, 2000, "Effect of sequence variation in meningococcal PorA outer membrane protein on the effectiveness of a hexavalent PorA outer membrane vesicle vaccine", <i>Vaccine</i> , 18:2476-2481
BJ	MOE et al. 1999, "Differences in Surface Expression of NspA among <i>Neisseria meningitidis</i> Group B Strains", <i>Infection and Immunity</i> , 67:5664-5675.
BK	MOE et al. 2001, "Functional Activity of Anti- <i>Neisseria meningitidis</i> Surface Protein A Monoclonal Antibodies against Strains of <i>Neisseria meningitidis</i> Serogroup B", <i>Infection and Immunity</i> , 69:3762-3771.
BL	MOLAGES et al., 1994, "Immune Response of Brazilian Children to a <i>Neisseria meningitidis</i> Serogroup B Outer Membrane Protein Vaccine; Comparison with Efficacy", <i>Infection and Immunity</i> , 62: 4419-4424.
BM	PIZZA et al. 2000 "Identification of Vaccine Candidates Against Serogroup B <i>Meningococcus</i> by Whole-Genome Sequencing", <i>Science</i> 287:1816-1820.
BN	ROUPPE VAN DER VOORT et al., 2000, "Immunogenicity studies with a genetically engineered hexavalent PorA and a wild-type meningococcal group B outer membrane vesicle vaccine in infant cynomolgus monkeys", <i>Vaccine</i> , 18:1334-1343.
BO	SACCHI et al., 1998, "Correlation between Serological and Sequencing Analyses of the PorB Outer Membrane Protein in the <i>Neisseria meningitidis</i> Serotyping System", <i>Clin. Diag. Lab. Immunol.</i> 5:348-354.
BP	SACCHI et al., 2000, "Diversity and Prevalence of PorA Types in <i>Neisseria meningitidis</i> Serogroup B in the United States", <i>Journal of Infectious Diseases</i> , 182:1169-1176.

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BQ	SAUKKONEN et al. 1988, "Monoclonal Antibodies to the Rough Lipopolysaccharide of <i>Neisseria meningitidis</i> Protect Infant Rats From Meningococcal Infection" <i>Journal of Infectious Diseases</i> , 158: 209-212.
BR	SHAO-QING, et al., 1981, "Three new serogroups of <i>Neisseria meningitidis</i> ", <i>J. Biol. Stand.</i> 9: 307-315.
BS	SLATERUS, K. W., 1961, Ant. V. Leeuwenhoek, "Types of Meningococcal Isolated from Carriers and Patients in a Non-Epidemic Period in the Netherlands", <i>J. Microbiol. Serol.</i> 29: 265-271
BT	STEPHENS et al. 1991, "Insertion of Tn916 in <i>Neisseria meningitidis</i> Resulting in Loss of Group B Capsular Polysaccharide", <i>Infection and Immunity</i> , 59: 4097-4107
BU	TAPPERO et al., 1999, "Immunogenicity of 2 Serogroup B Outer-Membrane Protein Meningococcal Vaccines", <i>JAMA</i> 281:1520-1572.
BV	WYLE et al., 1972, "Immunologic Response of Man to Group B Meningococcal Polysaccharide Vaccines", <i>J Infect. Dis.</i> 126: 514-522.
BW	ZOLLINGER, et al., 1979, "Complex of Meningococcal Group B Polysaccharide and Type 2 Outer Membrane Protein Immunogenic in Man", <i>J Clin. Invest.</i> 63: 836-848.
BX	NAESS, et al. 1998, "Human T-Cell Response after Vaccination with the Norwegian Group B Meningococcal Outer Membrane Vesicle Vaccine" <i>Infection and Immunity</i> , Vol. 66(3): 959-965.
BY	HANEBERG et al. 1998, "Intranasal Administration of a Meningococcal Outer Membrane Vesicle Vaccine Induces Persistent Local Mucosal Antibodies and Serum Antibodies with Strong Bactericidal Activity in Humans", <i>Infection and Immunity</i> , Vol. 66(4): 1334-1341.
BZ	WEDEGE et al. 1998, "Immune Response against Major Outer Membrane Antigens of <i>Neisseria meningitidis</i> in Vaccines and Controls Contracted Meningococcal Disease during the Norwegian Serogroup B Protection Trail", <i>Infection and Immunity</i> , Vol. 66(7): 3223-3231.
CA	LEHMANN et al. 1999, "Human Opsonins Induced during Meningococcal Disease Recognize Outer Membrane Proteins PorA and PorB", <i>Infection and Immunity</i> , Vol. 67(5):2552-2560.
CB	ROSENQVIST et al. "Human Antibody Responses to Meningococcal Outer Membrane Antigens after three Doses of the Norwegian Group B Meningococcal Vaccine", <i>Infection and Immunity</i> , Vol. 63(12): 46-42-4652.

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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